REDACTED DOCUMENTS RELATED TO DOCKET 7302

Defendants' Motion to Exclude the Opinions of Darren R. Hurst, M.D. and Supporting Memorandum of Law – Filed Redacted

Exhibit A – Filed Redacted

Exhibit D – Filed Redacted

Exhibit F – Filed Redacted

Exhibit G – Filed Redacted

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Defendants' Motion to Exclude the Opinions of Darren R. Hurst, M.D. and Supporting Memorandum of Law – Filed Redacted

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Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S MOTION TO EXCLUDE THE OPINIONS OF DARREN R. HURST, M.D., AND SUPPORTING MEMORANDUM OF LAW

(ASSIGNED TO THE HONORABLE DAVID G. CAMPBELL)

(ORAL ARGUMENT REQUESTED)

INTRODUCTION

Pursuant to Federal Rule of Evidence 702, and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny, Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard"), respectfully move to exclude certain expert opinion testimony offered by Darren M. Hurst, M.D. ("Dr. Hurst"), an

interventional radiologist. Bard's Motion is supported by the following Memorandum of Points and Authorities and any oral argument the Court may entertain.

MEMORANDUM OF POINTS AND AUTHORITIES

Bard seeks to exclude the following opinions of Dr. Hurst:

1. Bard filters had higher complication rates than other manufacturers' filters and an "unacceptable" rate of caudal migration.
2. Bard ignored safety signals with its filters, and elected not to perform additional studies to evaluate durability, safety, and efficacy, all while falsely representing superior safety, quality, and performance.
3. Bard failed to communicate to doctors that the Meridian® should be used instead of the Eclipse® and G2X® in patients like Ms. Mulkey, Ms. Jones, and Ms. Hyde.

Bard seeks to exclude these opinions on the grounds that Dr. Hurst is either not qualified to give these opinions, has failed to provide reliable, scientific methodology to support these opinions, and relies solely upon limited documents selected by plaintiffs' counsel to reach otherwise unsubstantiated conclusions. These opinions are unreliable and will not assist the trier-of-fact in determining the issues in this case.

ARGUMENT AND CITATION OF AUTHORITY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE DR. HURST

For an expert's opinion to be admissible under Federal Rule of Evidence 702, the Court must find that "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Rule 702 incorporates principles established in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), in which the Supreme Court charged trial courts with a gatekeeping role to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." (*Id.* at 589.) Ultimately, the objective of *Daubert* is "to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes

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the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). The proponent of expert testimony must demonstrate admissibility by a preponderance of proof. *Daubert,* 509 U.S. at 592 n. 10; *Lust By & Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). And "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). Under the above *Daubert* standard, the opinions discussed in this Motion are unreliable.

A fundamental requirement of Rule 702 is that the proposed scientific/technical testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." The Ninth Circuit has found that "[f]ederal judges *must* . . . *exclude* proffered scientific evidence under Rules 702 and 403 unless they are convinced that it speaks clearly and directly to [the] issue in dispute in the case, and that it will not mislead the jury." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1321 n.17 (9th Cir. 1995) (emphasis added).

The opinions of Dr. Hurst identified above will not assist the trier-of-fact and should be excluded. *See e.g., U.S. v. Frazier*, 387 F.3d 1244, 1262-63 (11th Cir. 2004) (also noting that expert opinion is not helpful to the trier of fact "when it offers nothing more than what lawyers for the parties can argue in closing arguments"); *In re: Trasylol Prods.. Liab. Litig.*, 709 F. Supp. 2d 1323, 1346 (S.D. Fla. 2010) (excluding testimony concerning regulatory history, FDA correspondence, and internal company documents, noting that the issues should be presented to the jury directly, not through an expert who "regurgitates them and reaches conclusory opinions . . . and invades the province of the jury."); *In re: Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1067 (D. Minn. 2007) (excluding testimony as "lay matters" and "conclusory statements about questions of fact masquerading behind a veneer of technical language" where plaintiffs proffered an expert to opine that Bayer ignored its toxicologists' concerns about Baycol's steep dose-response curve as it concerned Baycol's safety profile); *In re: Rezulin Prods. Liab. Litig.*, 309 F.

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Supp. 2d 531, 555 (S.D.N.Y. 2004) (excluding expert testimony concerning the alleged downplaying of hepatotoxic effects of Rezulin in the published literature based on internal documents, memos, and e-mails, finding that the issues constituted "lay matters" and would amount to arguing from the witness stand).

1. Dr. Hurst Is Not Qualified to Opine That Bard Failed to Comply with Some Duty to Notify Doctors and Patients of Allegedly Higher Complication Rates.

In his Rule 26 Report for each of the five bellwether plaintiffs, Dr. Hurst states "Bard failed to notify the operating physicians and the implanted patients of the much higher complication rates associated with the Recovery®, G2, and Eclipse filters, in comparison to the original predicate device, the Simon® Nitinol Filter, and competitor filters."[1] (Ex. A, Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, *Opinion 4(d)(i),* at 9.) Dr. Hurst also states that, based on adverse event reports/sales data, medical literature and internal Bard documents, the G2 filter had an "unacceptable risk of caudal migration." (*Id.* at *Opinion 4(d)(ii),* at 9-10.)

A. Dr. Hurst should not be permitted to opine that Bard filters had higher complication rates than other manufacturers' filters and an "unacceptable" rate of caudal migration.

Dr. Hurst is neither qualified to provide an opinion on what the complication rates are in Bard filters, nor is he qualified to say that they have "higher complication rates" as compared to any other IVC filters. He has not provided any scientific methodology which supports the reliability of that opinion. The two bases Dr. Hurst states for his opinion that there are "higher rates" in Bard filters are: (1) "I feel like . . . the risk of complications from the [Bard] filters is much higher in general in comparison to both permanent and other retrievable filters," (Ex. B, Hurst Dep. Tr., 255:19-256:9, August 7, 2017) and (2) his review of an article which purports to have gathered information on filter complications reported in other published studies of IVC filters. (Ex. C, Steven E. Deso, M.D., *et al., Evidence-Based Evaluation of Inferior Vena Cava Filter Complications*

[1] Bard attaches and cites Dr. Hurst's Rule 26 Report from the Debra Mulkey case herein, by way of example.

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Based on Filter Type, Semin. Intervent. Radiol. 2016; 33:93-100.) Dr. Hurst describes *Deso* as "a meta-analysis of all the filters . . . a combination of basically all of the literature up-to-date on IVC filters at that time. So there's multiple articles that would support that." (Ex. D, Hurst Dep. Tr., 33:17-34:15, July 21, 2017.) These bases for Dr. Hurst's opinions on rates are insufficient for several reasons.

Dr. Hurst is a medical doctor with a specialty in vascular and interventional radiology. (*Id.* at 7:13-14). There is no evidence in the record indicating that Dr. Hurst is a biostatistician or an epidemiologist. Consequently, what he "feels" about rates in Bard filters does not spring from any formal expertise in determining the rates of adverse events. With respect to his reliance on the *Deso* article ("*Deso*") as proof of this opinion, Dr. Hurst is not qualified, since he has no expertise in statistics or epidemiology, to give an expert opinion that the events reported in *Deso* are complete, accurate, or provide reliable rate information for Bard filters. Even if he were qualified to make such an analysis, Dr. Hurst has done no work to verify the information reported in *Deso*, to analyze what information may be missing, whether the information utilized was subject to biases making the information unreliable, and the extent to which one can or cannot draw the conclusions he reached from a statistical or epidemiological standpoint. (Ex. B, Hurst Dep. Tr., 267:14-269:12, August 7, 2017.)

When asked if there is any published study comparing Bard retrievable IVC filter rates head to head with other IVC filters, Dr. Hurst conceded that no such comparative study exists: "No one has done, though, a comprehensive study. That study is ongoing, it's called the PRESERVE trial." (Ex. D, Hurst Dep. Tr., 33:17-34:15, July 21, 2017.) Dr. Hurst adds "the reason the PRESERVE trial is ongoing right now and it was -- the reason that it was so important is that I think there was a recognition that the data for filters in general was lacking." (*Id.* 41:17–25)

Dr. Hurst also opines that the G2 filter had an "unacceptable risk of caudal migration," (Ex. A, Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, *Opinion 4(d)(i)*, at 9-10.) However, he conceded that "[t]he mere fact that a complication occurs

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doesn't mean that the risks outweighs the benefits? No, no. I mean, you have to -- you can't -- I guess you have to qualify that statement by saying you need to know the degree of risk of the complication in order to weigh it against the benefits." (Ex. D, Hurst Dep. Tr., 31:23-32:9, July 21, 2017.) However, Dr. Hurst does not provide record evidence about what the rate of caudal migration is for Bard filters, and he does not state his bases for concluding that the rate is "unacceptable." (*Id*. at 102:22-103:8) Dr. Hurst testified that his analysis to form this opinion amounted to his review and interpretation of a Bard internal document that discusses caudal migration. (Ex. B, Hurst Dep. Tr., 253:20-256:9, August 7, 2017.) He performed no independent analysis to determine the rate of caudal migration in Bard filters compared to the rate in competitive filters. (Ex. D, Hurst Dep. Tr., 60:11-61:7, July 21, 2017.) Other than *Deso*, he points to no study that shows the rates of caudal migration, in Bard filters, how that compares with caudal migration in other filters, or how that makes the frequency of this event "unacceptable." And he does not point to the FDA or any other agency or medical organization which has found this frequency to be "unacceptable". In sum, Dr. Hurst is unqualified to proffer his opinions regarding what the rates of caudal migration are in Bard filters, and he has failed to employ any scientific methodology to determine what those rates are, whether they are "unacceptable," and to whom.

Courts have limited the scope of an expert's opinions where they venture into areas outside the scope of their qualifications. *See e.g. Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 188 (E.D.N.Y. 2013) (finding that a physician who had significant clinical experience with the medical device at issue went "well beyond the 'reasonable confines' of his clinical expertise" when offering opinions regarding biomedical engineering and material science, and that therefore the physician was not qualified to offer such opinions); *In re Silicone Breast Implants Litig.*, 318 F.Supp.2d 879, 902 (C.D.Cal. 2004) (excluding opinions about the defendant's failure to conduct tests proffered by the plaintiff's expert, who had worked in quality control for a pharmaceutical company, published papers about medical devices, and holds patents on medical devices, on the

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grounds that such experience is insufficient foundational knowledge for offering opinions on testing); *Kruger v. Johnson & Johnson Professional, Inc.*, 160 F. Supp. 2d 1026, 1031 (S.D. Iowa 2001) (finding that a metallurgist was unqualified to offer design opinions regarding bone screws where he had no experience in the design of medical implants or any other medical devices). Courts have similarly limited the scope of an expert's opinions where that expert failed to use scientific methodology to show the reliability of his assertions. Indeed, "'[t]he reliability prong mandates that expert opinion be grounded in the methods and procedures of science and . . . be more than unsupported speculation or subjective belief.'" *Harris v. Spine*, 39 F. Supp. 3d 846, 850 (S.D. Miss. 2014) (quoting *Johnson v. Arkema, Inc.*, 685 F.3d 452, 459 (5th Cir. 2012)) (ellipsis in original). The proponent of expert testimony must demonstrate admissibility by a preponderance of proof. *Daubert, 509 U.S.* at 592 n. 10. "'The expert's assurances that he has utilized generally accepted scientific methodology is insufficient.'" *King v. Synthes (U.S.A.)*, 532 F. Supp. 2d 828, 832 (S.D. Miss. 2006) (quoting *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998)).

Like the many courts that have excluded or limited the scope of opinions outside an expert's particular area of qualifications, and for lack of reliability, the Court should exclude Dr. Hurst's testimony about rates because he has no formal education, experience, training, or foundational knowledge to determine from any source what the "rates" are, admits there are no studies which provide comparative rates between IVC filters on the market, and he has done nothing to verify the reported information in *Deso* which he relies so heavily upon as the basis for these opinions.

2. Dr. Hurst is Not Qualified to Say Bard Ignored Safety Signals With Its Filters, and Elected Not to Perform Additional Studies to Evaluate Durability, Safety, and Efficacy, All While Falsely Representing Superior Safety, Quality, and Performance.

In a series of opinions that are closely related, Dr. Hurst claims that: (1) Bard ignored early safety signals from adverse event reports, sales data, medical literature, its own testing, and internal risk analysis with the Recovery, G2, and Eclipse filters (Ex. A,

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Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, *Opinion 4(d)(ii)*, at 9-10); (2) Bard chose not to conduct additional studies to further evaluate safety, durability, and efficacy (*Id*. at *Opinion 4(d)(vi)*, at 11)[2]; and (3) Bard falsely represented improvements in newer generation filters through marketing materials. (*Id*. at *Opinion 4(d)(v)*, at 11.)[3]

Dr. Hurst is not qualified to offer opinions about the design, testing, and marketing of Bard filters, or any of Bard's internal decisions or follow-up diligence related to its filters. Again, he is not trained as a biomedical engineer, or in the design, manufacture, and labelling of medical devices, (Ex. E, Hurst Dep. Tr., 21:18-22:17, August 19, 2016.), and he admits that he is not an FDA regulatory expert. (Ex. D, Hurst Dep. Tr., 42:4-16, 69:23-70:19, July 21, 2017.) Once again, the case law cited in Section 1, *supra*, provides examples where courts have excluded or limited the scope of opinions where the expert ventures outside of his or her particular expertise.

In addition, Dr. Hurst also fails to offer any methodology to support these opinions. His foundation comes almost exclusively from twenty-four (24) Bard emails and documents, and select depositions from this litigation, provided to him by plaintiffs' counsel. (Ex. A, Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, *Appendix*, at 15-17.);

[2] Dr. Hurst also comments in *Opinion 4(d)(vi)*, that Bard conducted a "decade long open experiment with Bard retrievable filters" instead of "perform[ing] studies to further evaluate the safety, efficacy, and durability of their filters." Bard not only contends that this testimony should be excluded for the reasons stated in this Section (i.e. lack of qualification to offer these opinions and insufficient methodology and factual basis for these opinions), but also because this statement is unduly prejudicial to Bard under Federal Rule of Evidence 403.

[3] Dr. Hurst also goes beyond the realm of his experience in *Opinion 4(d)(v)*, when stating that Bard falsely represented the qualities of its newer generation filters through its marketing materials. Though Dr. Hurst has reviewed some Bard marketing materials and had personal experience with Mike Kirksey, the Bard sales representative assigned to his hospital, Dr. Hurst has not seen Mr. Kirksey in years. (Ex. D, Hurst Dep. Tr., 68:17-69:7, July 21, 2017.) In addition, Dr. Hurst testified that he stopped using Bard filters around the time the Meridian was on the market, does not know the rates of tilt and caudal migration for the Meridian, and does not know how Meridian® compares clinically to Eclipse or G2X (*Id*. at 102:5-104:14.) Finally, Dr. Hurst does not have any personal knowledge or data regarding what Bard marketing materials other physicians reviewed, or how those materials impacted their decision to implant one filter model over another.

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(Ex. D, Hurst Dep. Tr., 19:14-20, July 21, 2017.) Dr. Hurst also testified that he requested and/or received from plaintiffs' counsel a supplemental list of deposition transcripts and expert reports; however, to the extent those are not included in the Appendix to his Rule 26 Reports, Dr. Hurst testified that he did not review those materials prior to signing and serving his Rule 26 Reports. (Ex. D, Hurst Dep. Tr., 12:1-11, July 21, 2017.) In this case, Bard has produced over 8 million pages of documents, and the parties have conducted dozens of corporate witness depositions. Dr. Hurst has only reviewed but a small fraction of these materials. Not only does Dr. Hurst lack the qualifications to opine on the import of Bard documents related to design, testing, and risk analysis, but he has only reviewed a small portion of the total record evidence in this case, most of which was selected by the lawyers who retained him. Thus, even if he were qualified to comment on these documents, and Bard contends that the is not, he is missing a large part of the evidentiary context here, and simply cannot know what Bard has done or not done in the way of further evaluation, testing, or vetting of its internal data and risk analyses. Courts weigh the lawyer-selected provision of documents to experts heavily against whether the expert's opinions are based upon sufficient facts or data. *See, e.g.*, *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062, 1086-87 (D. Kan. 2002) (excluding an expert's opinion that was based upon preselected documents from counsel because the opinion did "not utilize sufficient facts and data and it is not the product of reliable principles and method"), *aff'd*, 356 F.3d 1326 (10th Cir. 2004); *In re TMI Litig.*, 193 F.3d 613, 698 (3d Cir. 1999) (affirming exclusion of a physician-expert's testimony as unreliable where the physician relied exclusively on documents supplied by plaintiff's counsel in arriving at her opinions).

Courts have excluded or limited the scope of opinions outside an expert's particular area of qualifications. Courts have also excluded expert testimony where such opinions are based on insufficient facts and data chosen by plaintiffs' counsel. Likewise, here, the Court should exclude Dr. Hurst's aforementioned opinions for all of the same reasons.

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3. Dr. Hurst is Not Qualified to Opine That Bard Failed to Communicate to Doctors That the Meridian® Should Be Used Instead of the Eclipse and G2X in Patients Like Ms. Mulkey, Ms. Jones, and Ms. Hyde.

In his Rule 26 Report for bellwether plaintiffs Debra Mulkey, Doris Jones, and Lisa Hyde, Dr. Hurst opines that Bard failed to communicate to doctors that the Meridian should be used instead of the Eclipse (in Ms. Mulkey and Ms. Jones), and the G2X (in Ms. Hyde) (Ex. A, Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, *Opinion 4(d)(iv)*, at 10-11.)

[redacted]. (Ex. H, August 24, 2011 Letter from FDA to Bard Peripheral Vascular, Inc. re Clearance for Meridian Jugular/Subclavian Delivery Kit) Consequently, Bard could not have offered its Meridian® filter to the implanting doctors in the Jones and Hyde cases, making Dr. Hurst's opinion on this issue inapplicable in those cases.

[redacted], (Ex. A, Hurst 6/5/17 Rule 26 Report as to Debra Mulkey, at 4.) after the date that the Meridian was available; however, Dr. Hurst should not be permitted to argue that the bellwether plaintiffs' treating physicians should have implanted Meridian filters in them, but did not because Bard supposedly failed to notify them that the purportedly "safer" Meridian was on the market at the time those plaintiffs had their Bard filters implanted. Dr. Hurst does not know the specific circumstances behind the treating physicians' choice of filters in their respective patients, what they were aware of or not aware of with respect to the Meridian filter, and how Meridian compares clinically to Eclipse or G2X (Ex. D, Hurst Dep. Tr., 102:5-103:20, July 21, 2017.)

Based on the record evidence, Dr. Hurst does not know what information Bard shared with the physicians who implanted Bard filters in other patients. He does not know how Bard informed other physicians about new filter models, or the details of any conversations other physicians had with their respective Bard sales representatives. He also does not know the purchasing protocols for other physicians' respective hospitals, how other physicians' hospitals cycle through their filter stock, what considerations other hospitals' purchasing departments make when selecting a device, and whether other physicians have any input on what products their hospitals purchase from manufacturers. Accordingly, Dr. Hurst is speculating when he claims physicians who treated bellwether plaintiffs did not implant the Meridian in patients because Bard failed to communicate to doctors that the Meridian should be used instead of the Eclipse or the G2X.

As demonstrated by the case law cited in Section 1, *supra*, courts have excluded or limited the scope of opinions outside an expert's particular area of qualifications. Likewise, here, the Court should exclude Dr. Hurst's opinions and testimony that Bard failed to communicate to doctors that the Meridian should be used instead of the Eclipse in Ms. Mulkey's case.

CONCLUSION

Because Dr. Hurst is unqualified to opine about the topics identified above, failed to use scientific methodology, and/or simply relied upon limited documents selected by plaintiffs' counsel, his opinions are unreliable, will not help the jury determine the issues, and should be excluded.

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DATED this 24th day of August, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that August 24th 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

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REDACTED DOCUMENTS RELATED TO DOCKET 7302

Exhibit A – Filed Redacted

Expert Report

Debra Mulkey v. CR Bard Inc.

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Director Vascular and Interventional Radiology
Department of Radiology
St. Elizabeth Health System
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Table of Contents

1. My name is Darren R. Hurst. I am a full time physician and fellowship trained vascular and interventional radiologist. The discipline of vascular and interventional radiology involves the diagnosis, treatment and management of medical diseases and health conditions through imaging and targeted, image-guided, minimally invasive surgical procedures. The procedures I perform involve the introduction of medical devices into the human body under image guidance such as ultrasound, CT, and fluoroscopy. Often, this involves the use of needles, guidewires, catheters, balloons, stents, drains, and other medical devices. My education, training, and experience are detailed in my CV which is in appendix A of this report. My practice is located in Edgewood, Kentucky, and serves the Greater Cincinnati, Ohio area. I am familiar with the issues, subject matter, and topics involved in this litigation. I have personal experience with the use of both permanent and retrievable inferior vena cava filters for the prevention of pulmonary embolism. As part of my practice, I regularly implant and retrieve inferior vena cava filters. I am familiar with the relevant medical literature that addresses the issues concerning IVC filters, including, but not limited to, the indications and contraindications for use, placement, complications, and risks and benefits of the devices. I am also familiar with and have utilized multiple different types of filter devices including the Bard Simon Nitinol Filter®, Recovery Filter®, G2 Filter®, G2X Filter®, Eclipse® and Denali Filter®. This experience, in combination with my education and training in the field of medicine, and specifically, the field of Vascular and Interventional Radiology, has formed the basis for my opinions rendered in this litigation.

2. Case Specific Materials Reviewed
    a. Medical Records:
        i. [redacted]
        ii. [redacted]
        iii. [redacted]
        iv. [redacted]
        v. [redacted]

vi. [redacted]
vii. [redacted]

b. Imaging Reviewed:

[redacted]

c. Depositions:
   i. Debra Mulkey 2/8/17.
   ii. Roderick Tomkins, M. D. 4/11/17.
   iii. Mark Workman, M.D. 3/28/17.
   iv. Scott Karch 3/20/17

d. IFU
   i. Bard Eclipse and Meridian Filters.

e. Bard Documents and Depositions (See Appendix)

f. Expert Reports
   i. Drs. Kinney, Roberts, and Kalva
   ii. Mark Eisenberg, M. D.
   iii. I have reviewed these reports, I agree with them, and I adopt the opinions and bases for those opinions set forth therein.

3. Case Summary:
   a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

[redacted]

f. [redacted].

g. [redacted]

h. [redacted]

4. Opinions:

a. Summary of clinical events:

i. [redacted]

ii. [redacted].

b. Reasonable expectations of physicians for medical devices:

i. In the everyday practice of medicine, I along with my colleagues/implanting and treating physicians have expectations of medical device companies like CR Bard and Bard Peripheral Vascular (referred to collectively in this report as "Bard") when they design, manufacture, market, and sell medical devices. Fulfilling these expectations in their design, testing, manufacturing, warning, and marketing of IVC Filters allows physicians to properly and completely obtain informed consent from their patients. Fulfillment of these expectations also allows physicians to select the appropriate IVC filter and make appropriate therapeutic decisions on behalf of their patients whether an IVC filter is indicated or considered as a therapeutic option, and whether to use or not use a particular type of IVC filter.

ii. Moreover, a patient has reasonable expectations on what he/she should know in the same or similar circumstances as a reasonable patient who has been prescribed or has considered having an IVC filter implanted.

c. Informed Consent:

i. The AMA Code of Medical Ethics - CHAPTER 2: OPINIONS ON CONSENT, COMMUNICATION & DECISION MAKING, *2.1.1 Informed Consent* states: Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should: (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision. (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about: (i) the diagnosis (when known); (ii) the nature and purpose of recommended interventions; (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.

https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics- chapter-2.pdf.

ii. The AMA Code of Medical Ethics' Opinion 8.08 – Informed Consent states: The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the

patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information (see Opinion 8.122, "Withholding Information from Patients").

Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians need not communicate all information at one time, but should assess the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate.

http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.

I have adopted the above AMA Codes in my daily practice and, in my opinion, they represent the standard of care relative to Informed Consent, Patient Communication and Decision Making.

d. Failure to notify:

i. Given the above responsibilities of the medical device manufacturer to the patient and the physician, and the physician to the patient, it is my opinion that Bard failed to notify the operating physicians and the implanted patients of the much higher complication rates associated with the Recovery®, G2®, and Eclipse® filters in comparison to the original predicate device, the Simon Nitinol Filter®, and competitor filters. Instead, Bard continued to represent its filters as having superior safety, quality and performance. (Example: G2 Brochure: "…strength and stability to a new level.")

ii. There were multiple early safety signals with the Recovery®, G2®, and Eclipse® filters. These signals came from adverse event reports/sales data, from reports in the medical literature, from Bard's internal risk analysis, and from Bard's own in vitro testing indicating low migration resistance compared to other filters, and in some instances failing to meet Bard's arbitrary minimum threshold for migration

resistance under a variety of foreseeable circumstances. For example, Bard's own internal risk analysis deemed the G2 filter (a filter identical to the Eclipse filter used in Ms. Mulkey other than electropolishing) to pose an "unacceptable risk" of caudal migration.

iii. [redacted] the G2/G2X, had significant issues with safety, Bard continued to market the device for both permanent and retrievable indications in the prevention of PE from DVT. During this time, Bard acknowledged design flaws that needed to be corrected, but instead chose to inappropriately utilize the data from the Grassi paper, and ignore their in house studies, risk analysis and the current medical literature, to justify the high complication rates and continued marketing practices. In essence, Bard chose to keep the product on the market until a new product was released rather than focusing on its duty to remove unsafe devices from the market.

iv. [redacted] Bard's next generation filter, the Meridian, was already being marketed and sold – having been launched in August of 2011. Among other changes, the Meridian filter was the first Bard filter to add caudal anchors for the purpose of "improving caudal migration resistance and tilt performance." As Bard was aware, the Eclipse filter (identical to the G2 and G2X filters with exception of electropolishing) suffered from a significant increased safety risk of caudal migration (a risk which Bard internally deemed "unacceptable") over competitor filters, and even earlier Bard filters (including the Simon Nitinol). Bard was also aware at that time that caudal migration leads to tilt, perforation/penetration, complicated or high risk retrievals and fracture. All of this was despite Bard initiating an internal project to correct caudal migration of the G2 filter beginning in February of 2006, a fact that was not passed on to physicians or patients, and making no changes to address those caudal migration problems until launch of the Meridian in August of 2011 – more than 5 years later. Moreover, despite awareness of the need to correct the caudal migration problem with its filters, Bard launched the G2X and Eclipse, filters to which no changes were made to address the caudal migration safety risk, prior to launching the Meridian. Despite all of this, Bard continued selling the [redacted]

[redacted] those filters from medical facilities, and did nothing to communicate to physicians and patients that the Meridian should be used in lieu of the Eclipse. In my opinion, Bard should have never launched the Eclipse without the safety design changes required by the unacceptable risk of caudal migration the company knew existed with the G2 by late 2005/early 2006. Having made that choice to launch the Eclipse without these important patient safety design changes, Bard should have stopped selling the Eclipse and removed it from all medical facilities at the time it launched the Meridian filter. [redacted] the Meridian attempted to correct, including caudal migration, fracture, perforation and tilt of her filter.

v. In addition, Bard's marketing materials falsely represented newer generation devices as having greatly improved strength and stability when many of the changes in the devices from generation to generation were minimal and unproven in their impact on safety and efficacy.

vi. Bard elected not to perform studies to further evaluate the safety, effectiveness and durability of their filters. Instead, they embarked on a long term plan to evolve their filter through multiple generations while making small incremental changes to each generation in response to the safety issues that were arising in real time in patients that were unknowingly participating in a decade long open experiment with Bard retrievable filters.

vii. Had I been Ms. Mulkey's implanting physician, and aware of the safety issues that were known to Bard at the time of implantation of this device [redacted] I would have also advised my partners and colleagues to do the same. It is my opinion that Bard did not adequately warn physicians, including Ms. Mulkey's implanting physician, of important safety risks and issues associated with its filters of which it was aware. [redacted] seems to agree based on his deposition testimony. As one example, he testified "I wouldn't use the filter if I was aware that deaths were occurring concurrently with me placing these filters". (Mulkey Deposition pg. 53, lines 21-23).

e. Failure of the Bard Eclipse® Filter in Debra Mulkey:

i. [redacted] Given this backdrop, I render the following opinions:

1. [redacted] t.

2. [redacted]

3. [redacted]

4. [redacted]

5. [redacted]

.

6. [redacted]

7. [redacted]

8. [redacted]

9. [redacted]

[redacted]f

f. My opinions are based on the reasonable expectations I and other similarly situated physicians have in regards to the responsibilities of a medical device manufacturer in regard to the design, marketing, sales, and performance of their medical devices.

g. My opinions are based on my review of scientific and medical literature, the materials and medical records/films in this case, Bard internal documents, depositions, expert reports, and my clinical experience, education and training. I did my own medical literature research and review, as well as reviewing literature provided to me by the plaintiff's counsel.

h. In rendering my opinions in this matter, I took into consideration Ms. Mulkey's co-morbidities, medical history and preexisting problems.

i. All of my opinions are to a reasonable degree of medical and scientific certainty.

j. I understand that discovery is ongoing in this case. There may be additional information in the form of medical literature, expert reports, depositions, and case material. I reserve the right to amend my opinions if further pertinent information is discovered/obtained.

Darren R. Hurst, M. D.

June 5, 2017

APPENDIX

Bard Materials and Depositions Reviewed:

1. Janet Hudnall Email to David Rauch dated 2/26/04
2. Natalie Wong Email to Doug Uelmen dated 5/20/04 and attachment
3. Natalie Wong Email to Doug Uelmen dated 5/27/04
4. Health Hazard Evaluation from David Ciavarella dated 12/17/04
5. G2 Perforations from Christopher Ganser dated 11/10/05
6. G2 Caudal Migrations from David Ciavarella dated 12/27/05
7. G2 Filter System - indicated for retrieval
8. G2 Filter System - Patient Questions & Answers
9. SWOT - Objective: Increase Revenue and Capture More Market Share
10. Monthly Global PV Report from John McDermott dated 2/10/06
11. Health Hazard Evaluation from David Ciavarella dated 2/15/06
12. G2 Caudal Migration Update dated 3/2/06
13. G2 Fracture Report November 2008
14. G2 and G2X Fracture Analysis dated 11/30/08
15. BARD IVC Filter Program May 2009 – Mike Randall
16. Letter from Stacy Taiber to Brent Adamson, M.D.
17. Filter Naming Memo from Bill Little dated 4/27/10
18. Eclipse 510(k) sections on changes to filter from predicate

19. Eclipse Product Performance Specification for Migration from Design History File

20. Meridian Product Performance Specification for Caudal Migration from Design History File

21. Meridian Value Proposition from Design History File

22. Meridian Commercialization Plan dated 10/1/10

23. G2 Platinum PowerPoint

24. Scott Karch Email to Dr. Thomas dated 3/6/12

25. Brian Barry Deposition - 1/31/14

26. Robert Michael Carr, Jr. Deposition - 4/17/13

27. Robert Michael Carr, Jr. Deposition - 10/29/14

28. Robert Michael Carr, Jr. Deposition - 11/5/13

29. Clement J. Grassi, M.D. Deposition - 7/30/14

30. Clement J. Grassi, M.D. Deposition - 8/27/14

31. Clement J. Grassi, M.D. Deposition - 9/24/14

32. Murray Asch, M.D. Deposition – 5/2/16

33. Kay Fuller Deposition – 1/11/16

34. David Ciavarella, M.D. Deposition – 11/12/13

35. Christopher Ganser Deposition – 10/11/16

36. Janet Hudnall Deposition – 11/1/13

37. John Mcdermott Deposition – 2/5/14

38. Gin Shultz Deposition – 1/30/14

39. Douglas Uelmen Deposition – 10/4/14

40. Carol Vierling Deposition – 5/11/16

41. Natalie Wong Deposition – 10/18/16

42. Steven Williamson Deposition – 9/7/16

43. Medical Monitoring 30(b)(6) Deposition (John Van Vleet) – 1/17/17

Literature Reviewed:

MEDICAL ARTICLES	
TITLE	AUTHOR(S)
Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study	Binkert
In Vitro Metal Fatigue Testing of Inferior Vena Cava Filters	Bjarnason
Comparison of the Recovery and G2 Filter as Retrievable Inferior Vena Cava Filters	Cantwell
Quality Improvement Guidelines for the Performance of Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Caplin
Complications Encountered with the Use of the Greenfield Filter	Carabasi
Prophylactic and Therapeutic Inferior Vena Cava Filters to Prevent Pulmonary Emboli in Trauma Patients	Carlin
Update on Vena Cava Filters	Carman
G2 Inferior Vena Cava Filter: Retrievability and Safety	Charles
Prophylactic Inferior Vena Cava Filters: Do They Make a Difference in Trauma Patients? (abstract only)	Cherry
Complications of vena cava filters: A comprehensive clinical review	Cipolla

TrapEase Inferior Vena Cava Filter Placed via the Basilic Arm Vein: A New Antecubital Access	Davison
Removal of Fractured Inferior Cava Filters: Feasibility and Outcomes	Dinglasan
Celect Inferior Vena Cava Wall Strut Perforation Begets Additional Strut Perforation	Dowell
Perforation of the IVC: Rule Rather Than Exception After Longer Indwelling Times for the Gunther Tulip and Celect Retrievable Filters	Durack
"Reporting the Impact of Inferior Vena Cava Perforation By Filters" JOURNAL OF VASCULAR SURGERY; Vol. 55, No. 1	Wood
PRESERVE Study to be a Comprehensive Evaluation of Inferior Vena Cava Filter use	Endovascular Today
Clinical Experience with the Antecubital Simon Nitinol IVC Filter	Engmann
Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use	FDA
Percutaneous Inferior Vena Caval Filters: Follow up of Seven Designs in 320 Patients	Ferris
Medical Literature and Vena Cava Filters	Girard
Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Grassi
Vena Caval Occlusion after Simon Nitinol Filter Placement: Identification with MR Imaging in Patients with Malignanacy	Grassi
Long-Term Follow-up of the Antheor Inferior Vena Cava Filter	Harries
Retrieval of the Recovery Filters after Arm Perforation, Fracture, and Migration to the Right Ventricle	Hull
Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration	Hull
Single Institution Prospective Evaluation of the Over-the-Wire Greenfield Vena Caval Filter	Johnson
Vena Cava Filter Fracture: Unplanned Obsolescence	Johnson

Decision Analysis of retrievable inferior vena cava filters in patients without pulmonary embolism	Morales
Recovery Vena Cava Filter: Experience in 96 Patients	Kalva
Practice Patterns and Outcomes of Retrievable Vena Cava Filters in Trauma Patients: an AAST Multicenter Study	Karmy-Jones
Guidelines for the Use of Optional (Retrievable and Convertible) Vena Cava Filters	Kaufman
Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference	Kaufman
Development of a Research Agenda for Inferior Vena Cava Filters: Proceedings from a Multidisciplinary Research Consensus Panel	Kaufman
Update on Inferior Vena Cava Filters	Kinney
High Risk Retrieval of Adherent IVC Filters: Techniques and Management of Thrombotic Complications	Kuo
High-Risk Retrieval of Adherent and Chronically Implanted IVC Filters: Techniques for Removal and Management of Thrombotic Complications	Kuo
Modified Loop Snare Technique for the Removal of Bard Recovery, G2, G2 Express, and Eclipse Inferior Vena Cava Filters	Lynch
Removal of the G2 filter: differences between implantation times greater and less than 180 days	Lynch
Complications of the Nitinol Vena Caval Filter	McCowan
Indications for Vena Cava Filters for Recurrent DVT	Miller
Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters	Millward
Improving Inferior Vena Cava Filter Retrieval Rates: Impact of a Dedicated Inferior Vena Cava Filter Clinic	Minocha
Realistic expectations and candidate selection for entry level vascular technologist in a busy laboratory	Mutyala

Letter to the Editor: A Complication of a G2 Bard Filter	Nazzal
Complications Related to Inferior Vena Cava Filters: A Single-Center Experience	Nazzal
Long-term Follow-up of the Bird's Nest IVC Filter	Nicholson
Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade	Nicholson
Refrain, Recover, Replace	Nicholson
Correction to Article About Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters	Nicholson
Removal of Retrievable Inferior Vena Cava Filters with Computed Tomography Findings Indicating Tenting or Penetration of the Inferior Vena Cava Wall	Oh
Recovery G2 Inferior Vena Cava Filter: Technical Success and Safety of Retrieval	Oliva
Recovery G2 vena cava filter retrievability study	Oliva
Intracardiac Migration of Inferior Vena Cava Filters	Owens
Long-term Results of the Simon Nitinol Inferior Vena Cava Filter	Poletti
Aortic Pseudoaneurysm after Penetration by a Simon Nitinol Inferior Vena Cava Filter	Putterman
Complications of Inferior Vena Cava Filters	Ray
Outcomes with Retrievable Inferior Vena Cava Filters: A Multicenter Study	Ray
Medical Devices and the FDA Approval Process	Redberg
Simon Nitinol Inferior Vena Cava Filter: Initial Clinical Experience	Simon
Vena Caval Filters	Smith
Is Market Growth of Vena Cava Filters Justified?	Smous
Embedded Inferior Vena Cava Filter Removal: Use of Endobronchial Forceps	Stavropoulos
Complications of Vascular Access Procedures in Patients with Vena Cava Filters	Streib

Fracture and Distant Migration of the Card Recovery® Filter: A retrospective Review of 363 Implantations for Potentially Life-Threatening Complications	Tam
Vena Tech Vena Cava Filter: Experience and Early Follow-Up	Taylor
Management if Severe Vena Cava Filter Tilting: Experience with Bard G-2 Filters	Turba
FDA Safety Communication: Removing Retrievable Inferior Vena Cava Filters	U.S. Food and Drug Administration
Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: Incidence, Clinical Consequences, and Outcomes of Removal Attempts	Vijay
Retrievability and Device-Related Complications of the G2® Filter: A Retrospective Study of 139 Filter Retrievals	Zhu
Data Desert for Inferior Vena Caval Filters: Limited Evidence, Supervision, and Research	Bikdeli
Inferior vena cava filters	Duffett and Carrier
Vena Cava Filter Use in Trauma and Rates of Pulmonary Embolism, 2003-2015	Cook

Curriculum Vitae:

Darren R. Hurst, M. D.

Personal Information:

Address: 3325 Stettinius
Cincinnati, OH 45208
Phone: 513.403.7018
E-mail: dhurst@cinci.rr.com

Education:

Fellowship in Vascular and Interventional Radiology
University of Michigan Medical Center
1999-2000

Residency in Diagnostic Radiology
University of Michigan Medical Center
Dept. Award for Research Excellence 1999
1995-1999

Doctor of Medicine
University of Cincinnati College of Medicine
AOA Honor Society 1994-95
1991-95

B. A. in Zoology
Miami University, Oxford, Ohio
Cum Laude with University Honors
1987-91

Employment Experience:

Radiology Associates of Northern Kentucky
Managing partner
Regional multispecialty radiology and imaging group
2001-Present

Director Vascular & Interventional Associates
Division of Radiology Associates of NKY
Private practice VIR group
2003-Present

Director VIA Vein Center

Comprehensive Vein Center
2013-Present

Chief of Vascular & Interventional Radiology
St. Elizabeth Health System
2003-Present

Director IR Spine Intervention
St. Elizabeth Spine Center
St. Elizabeth Health
2009-2016

Physician Trainer for Spine Intervention
Stryker International
2011-2015

Hospital Affiliations:

St. Elizabeth Health
Edgewood Campus
1 Medical Village Drive
Edgewood, Kentucky 41017
859-344-2000

St. Elizabeth Health
Covington Campus
401 East 20th Street
Covington, Kentucky 41014
859-292-4000

St. Elizabeth Health
Ft. Thomas Campus
85 North Grand Avenue
Ft. Thomas, Kentucky 41075
859-572-3100

St. Elizabeth Health
Florence Campus
7380 Turfway Road
Florence, Kentucky 41042
859-962-5200

Private Practice Office:

Vascular and Interventional Associates
VIA Vein Center
Center for Spine Health
375 Thomas More Parkway
Crestview Hills, KY 41017
859-341-4841

Certification: ABR Certified in General Diagnostic Radiology 1999

ABR CAQ Board Certification
Vascular and Interventional Radiology 2001

ABR MOC/CAQ 10yr Recertification
Vascular and Interventional Radiology 2011

Kentucky License #35686
Ohio License #4536
Indiana License #010682666A

Professional Organizations:

RSNA: 1995
ARRS: 1995
ACR: 1998
SIS: 2010
SIR: 1999
ACP: 2015

Publications:

Hurst DR, Forauer AR, Bloom JR et al: Diagnosis and Endovascular Treatment of Iliocaval Compression Syndrome. J Vasc Surg 34(1):106-13, 2001.

Hurst DR, Kazerooni EA, Williams DM, Stafford-Johnson D, Platt JF, Prince MR: Diagnosis of Pulmonary Embolism: Comparison of MR Angiography and CT Angiography in Canines. *JVIR* 10:309-318, 1999.

Dong Q, **Hurst DR**, Wienmann HJ, Chenevert TL, Londy FJ, Prince MR: Magnetic Resonance Angiography With Gadomer-17: An Animal Study Original Investigation. *Investigative Radiology* 33:699-708, 1998.

Donnelly LF, **Hurst DR**, Strife JL, Shapiro RM: Plain Film Assessment of Pulmonary Flow in the Neonate with D-Transposition of the Great Vessels. *Pediatric Radiology* 25:195-7, 1995.

Research:

VOYAGER PAD Study: An international, multicenter, randomized, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularization procedures. Lead Investigator St. Elizabeth Health System 2014-present.

ATTRACT Study: a multicenter randomized trial to evaluate pharmacomechanical catheter-directed thrombolysis for the prevention of postthrombotic syndrome in patients with proximal deep vein thrombosis. Lead Investigator St. Elizabeth Health System 2013-present.

The CAPTURE registry: analysis of strokes resulting from carotid artery stenting in the post approval setting: timing, location, severity, and type. Co-investigator St. Elizabeth Health System 2005-2007.

The Fibroid Registry for outcomes data (FIBROID) for uterine embolization. Lead Investigator St. Elizabeth Health System 2001-2005.

Testimony List:

1. Susan Gail Smith v. St. Mary's Medical Center et al. 8/11/2015
2. Barbara Bongiorno v. Phillip Adler M. D.; St. John Macomb Hospital 1/21/2016
3. James Alley v. Hillcrest Medical Center et al. 3/15/16
4. Edith Fish v. Diallo et al. 11/7/2016
5. Austin v. CR Bard Inc. 8/19/16
6. Austin v. CR Bard Inc. 11/16/16

Fee Schedule:

1. My current fee for the following medical legal activities is $500.00 per hour. This includes medical records review, review of depositions, literature searches, consultation time, preparation for deposition and trial testimony, oral or written reports, all travel time (billed as portal to portal), or any miscellaneous task as requested by client.
2. My current fee for all local deposition and trial activities is $750.00 per hour.
3. All out of area travel that requires an overnight stay is billed at $6000.00 per day. If I have to use a half day for travel or return from the location of trial or deposition, that will be billed at 3000.00 per half day. If I must cancel an entire office day to provide the requested services, an additional fee of $2000.00 per clinic/work day will be charged. Trial and out of area fees must be paid in advance of the date of travel.

REDACTED DOCUMENTS RELATED TO DOCKET 7302

Exhibit D – Filed Redacted

Deposition of:

Darren Robert Hurst , M.D.

July 21, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

Veritext Legal Solutions
1075 Peachtree St. NE , Suite 3625
Atlanta, GA, 30309
800.808.4958 | calendar-atl@veritext.com | 770.343.9696

Q. And we can take a break at anytime that you would like.
A. (Nodding head.)
Q. It's my understanding that you have a hard stop, so to speak, at 1:00?
A. Yes, I do.
Q. Okay. Could you state your full name for the record?
A. Darren Robert Hurst.
Q. And what is your business address, Dr. Hurst?
A. 375 Thomas More Parkway.
Q. And what is your profession?
A. Interventional radiologist.
MR. NORTH: Let me ask the court reporter to mark this as Exhibit 1.
(Thereupon, Defendants' Exhibit No. 1, a 3-page Defendants' Notice of Videotaped Deposition Duces Tecum of Darren R. Hurst M.D., with attachment, was marked for purposes of identification.)
BY MR. NORTH:
Q. Doctor, here's Exhibit 1, which is a copy of the notice of deposition for today's proceedings. Were you furnished a copy of that?

Q. But somewhere in your report, either in the appendix or on the initial pages, is listed all of the materials you had reviewed as of that date?

A. Correct.

Q. And anything on Exhibit 2, the supplemental list we received yesterday, that is not listed in your report would have been materials you received subsequent to the date of the report?

A. Yes.

Q. And then I would like to mark as Exhibit 4 -- I have clipped together the copies of the invoices you brought.

(Thereupon, Defendants' Exhibit No. 4, multiple pages of Tristate Medical Legal Consulting Invoices, was marked for purposes of identification.)

MR. O'CONNOR: Let's see what we've got here so far. I've lost track. 1 is the --

MR. DEGREEFF: The notice.

MR. O'CONNOR: The notice, okay.

THE WITNESS: Here.

BY MR. NORTH:

Q. Exhibit 4, Doctor, is that a set of

on November 1.

THE WITNESS: Oh, yes.

MR. O'CONNOR: I think. I'll double check that.

THE WITNESS: Yeah.

MR. BROWN: Going to impeach you on that.

THE WITNESS: Yeah.

MR. O'CONNOR: It felt like it was 6 days or 16 days.

THE WITNESS: I can check right now.

MR. O'CONNOR: Don't worry about it.

BY MR. NORTH:

Q. As far as the company documents, Bard documents, that you have reviewed in your work in this case, were those all furnished to you by the plaintiffs' attorneys?

A. No. I asked for some of them.

Q. Well, but they came from the plaintiffs' attorneys, correct?

A. Oh, yes, yeah. Sorry, I misunderstood your question.

Q. And based upon your original list and the list you have here, it looks like you've been given a total of, I don't know, 30 or 40 company

much or more, penetrated the IVC. So, you know, it's in total the amount of all of those complications occurring or all of those issues occurring with the filter.

They all occurred with the same filter; whereas, when you look at each one of the older permanent filters, those weaknesses were -- each one of them had its own singular weakness, but not all of those weaknesses at once.

MR. NORTH: Move to strike as nonresponsive.

BY MR. NORTH:

Q. Do you draw a distinction between the concept of penetration and perforation?

A. Penetration I think is probably the proper term for the way that a strut pierces through the inferior vena cava. Perforation probably is not the best term.

Q. But, again, I understand your testimony about combination of complications and rate of complications.

A. (Nodding head.)

Q. But the mere fact that a complication standing alone occurs with a filter doesn't mean that the risks outweigh the benefits?

MR. O'CONNOR: Object to the form of the question.

THE WITNESS: The mere fact that a complication occurs doesn't mean that the risks outweighs the benefits? No, no. I mean, you have to -- you can't -- I guess you have to qualify that statement by saying you need to know the degree of risk of the complication in order to weigh it against the benefits.

BY MR. NORTH:

Q. My whole question is premised on just the occurrence of it, not rate.

A. But you can't do that.

Q. Let me try it this way.

A. Okay.

Q. You implant filters --

A. Correct.

Q. -- even though you know they have the potential to fracture, correct?

A. Absolutely.

Q. And in those cases, you decide as a practitioner that the risks are outweighed by the benefits of that device?

A. Correct.

Q. And the same thing is true with

regard to migration, you implant filters knowing that they can migrate in some cases, correct?

A. Correct.

Q. And in those instances, you make the determination that the risks are outweighed by the benefits?

A. Correct.

Q. And the same is true with tilt?

A. Correct.

Q. And the same is true with penetration?

A. Absolutely. That's a judgment that you make with every device when you're given the information on the device. And you take the information that you have for the device versus the clinical situation and you make a decision.

Q. Can you cite to me any medical articles that discuss this -- what you've characterized as a combination of complication modes associated with Bard filters?

MR. O'CONNOR: Object to the form of the question.

THE WITNESS: I think we could look at the Deso article, if you would like, which is a meta analysis of all of the filters.

BY MR. NORTH:

Q. So you're saying that the Deso article suggests that Bard filters have a uniquely high combination of complication modes?

A. If you look at the table, yes, it does.

Q. Any other articles you can cite that support that opinion?

A. Well, well, the Deso article is a combination of basically all of the literature up-to-date on IVC filters at that time. So there's multiple articles that would support that. No one has done, though, a comprehensive study. That study is ongoing, it's called the PRESERVE trial.

Q. Are you privy to any of the preliminary results of the PRESERVE trial?

A. I am not.

Q. Are you participating in the PRESERVE trial?

A. No, I am not.

Q. Are any of the facilities at which you work participating in the PRESERVE trial?

A. No, they are not.

Q. On your opinion, on page 6 again.

is, what good is warning me about whether or not the patient could die from the device or not.

So the degree of complications also needs to be included in there, especially if the degree is higher than alternative devices or you may suspect that it's higher than an alternative device.

BY MR. NORTH:

Q. Have you ever seen in Instructions For Use for any medical device that included comparative complication rates between that device and competitive devices?

A. There are stent IFUs that do, yes.

Q. Are they quoting internal company analyses or are they citing to clinical studies?

A. Clinical studies.

Q. Are you aware of any controlled clinical studies, other than the ongoing PRESERVE trial, that compares complication rates between different types of filters?

A. No. Obviously, the reason the PRESERVE trial is ongoing right now and it was -- the reason that it was so important is that I think there was a recognition that the data for filters in general was lacking.

Q. Do you know whether the FDA will permit -- well, let me back up.
A. Sure.
Q. You're not expert -- an FDA expert?
A. No, I am not.
Q. Have you ever appeared before the FDA in any capacity?
A. No, I have not.
Q. Have you ever made the submission to the FDA in any capacity?
A. No.
Q. So you would not know one way or the other whether the FDA would permit a company to put comparative complication data in an IFU in the absence of a clinical study?
A. I do not know that.
MR. O'CONNOR: Objection to the form of the question.
BY MR. NORTH:
Q. Did the Bard IFUs discuss the clinical studies that had been done with the Bard filter?
A. I'm not sure whether they include the Everest trial for the G2. They did not. They include practice guidelines.

exactly correct.

MR. O'CONNOR: When you get to a point, let's take 3 or 4 minutes.

MR. NORTH: Just a minute. Let me ask one question about the Deso so we can come back.

BY MR. NORTH:

Q. You mentioned references to the Deso or Deso article?

A. Yes, sir.

Q. Have you made any independent -- or done any independent research to try to determine whether the authors of that study were comprehensive in the literature that they cited or used for the meta analysis?

MR. O'CONNOR: Object to the form of the question.

THE WITNESS: Based on the literature that is in their references section and the literature that I've seen on Medline, ClinicalKey, and JVIR, it pretty much includes all of the literature that I've seen.

BY MR. NORTH:

Q. If they had omitted a number of articles that demonstrated low complication rates

with Bard filters, then, the conclusions of their meta analysis would be suspect, right?

MR. O'CONNOR: Object to the form of the question.

THE WITNESS: Yes, they would be, but I have not been able to find those articles. If you have those, I would love to see them.

MR. NORTH: Okay. We can take a break.

MR. O'CONNOR: Thank you.

THE VIDEOGRAPHER: Off the record at 9:09.

(Brief recess.)

(Mr. Degreeff not present.)

THE VIDEOGRAPHER: We're back on the record at 9:18.

BY MR. NORTH:

Q. Doctor, looking at page 9 of your report, Exhibit 3 --

A. Before we do that, can we return back to your question?

Q. Somehow I knew that was coming. Yes.

A. Okay. So I had a chance to look in my folder to the articles that I had. There are not any articles that compare a permanent filter

a permanent filter?

A. Yes, it is.

Q. Do you think that the Gunther Tulip has acceptable complication rates for a permanent filter?

A. No, I do not, and we don't leave that filter in permanently.

Q. Do you think that the Gunther Tulip's complication rates are higher than those for the G2 and the Eclipse?

A. No, I do not.

Q. Do you think that they're lower than the G2 --

A. I do.

Q. -- and Eclipse?

A. Yes.

Q. You make -- offer a number of opinions about Bard's marketing of filters?

A. Yes.

Q. And those opinions are based upon the marketing documents you saw, correct?

A. Correct, yes.

Q. Are they based in any way on your personal experience with Bard sales personnel?

A. Yes, they are.

Q. Who were your --
A. Mike Kirksey.
Q. When is the last time you saw him?
A. I haven't seen him in years. He doesn't work for Bard anymore. He works for Endologix, and Endologix makes stent grafts and we don't do stent grafts at our institution.
Q. Have you reviewed any of Bard's bench testing of its filters?
A. I have seen some of that data, yes.
Q. Have you reviewed Bard's 510(k) submissions to the FDA?
A. I have not reviewed their 510(k) submissions.
Q. Did you review actual test reports of bench data?
A. I have seen the tables. So I don't know if it's the actual -- do you mean the whole report?
Q. Right.
A. No. All I've seen are the data tables.
Q. Have you seen any of the FDA correspondence to Bard regarding its IVC filters?
A. Yes.

Q. What sorts of correspondence?
A. I've seen the -- give me a moment.
Q. Are you referencing the warning letter?
A. Yes.
Q. Other than the warning letter, have you seen any of the Bard --
A. No, I have not.
Q. -- FDA correspondence?
A. I have not.
Q. And you haven't seen any of the various submissions that Bard has made to the FDA providing them with various test data and answering questions of the agency?
A. I have not.
Q. And because you're not a regulatory expert, you're not familiar with what materials of Bard that the FDA may have reviewed?
A. Correct.
Q. Now, my understanding is you do believe -- given the fact that you implant them still, you do believe that filters are appropriate in certain patients, correct?
A. Yes.
Q. And you would consider pulmonary

[redacted]

Q. Did you ever implant Meridian filters?

A. No. We had stopped using Bard filters at that time.

Q. Do you know the rates of tilt and caudal migration of the Meridian filter?

A. I do not know. I don't know if we know that.

Q. Do you know how they compare with the rate of tilt and migration for the G2 -- I mean, for the Eclipse?

A. I don't know.

Q. So you have not tried to do a study comparing the complication rates between the Eclipse and the Meridian, have you?

A. No, I haven't.

Q. You would agree that you are not an expert in device design, development, or manufacture, correct?

A. I am not an expert in device design, development, or manufacture; but I do work with medical devices every day and have seen hundreds and hundreds of devices.

Q. You indicated that you had not done any analysis of the comparative complication rate between the Eclipse and the Meridian. Have you done a comparative analysis of the complication rates between the G2 and the Eclipse?

MR. O'CONNOR: Form.

THE WITNESS: There's not much difference between the G2 and the Eclipse except for electropolishing, and I don't know if electropolishing has even been shown to have any

significant effect on the filter itself.
BY MR. NORTH:
Q. Well, I understand that you are -- you have a supposition that the rates should be similar --
A. Um-hmm.
Q. -- but that's not my question.
A. Okay.
Q. My question is: Have you done a comparative study of the complication rates of the Eclipse versus the G2?
MR. O'CONNOR: Objection.
THE WITNESS: I have not seen a comparative study, and I have not done one.
BY MR. NORTH:
Q. [redacted]
MR. NORTH: Sorry about that.
THE WITNESS: It's not my phone.
MR. O'CONNOR: Time to wake up.
BY MR. NORTH:
Q. [redacted]

REDACTED DOCUMENTS RELATED TO DOCKET 7302

Exhibit F – Filed Redacted

Expert Report

Doris Jones v. CR Bard Inc.

Darren R. Hurst, M. D.
Director Vascular and Interventional Radiology
Department of Radiology
St. Elizabeth Health System
1 Medical Village Drive
Edgewood, KY 41017

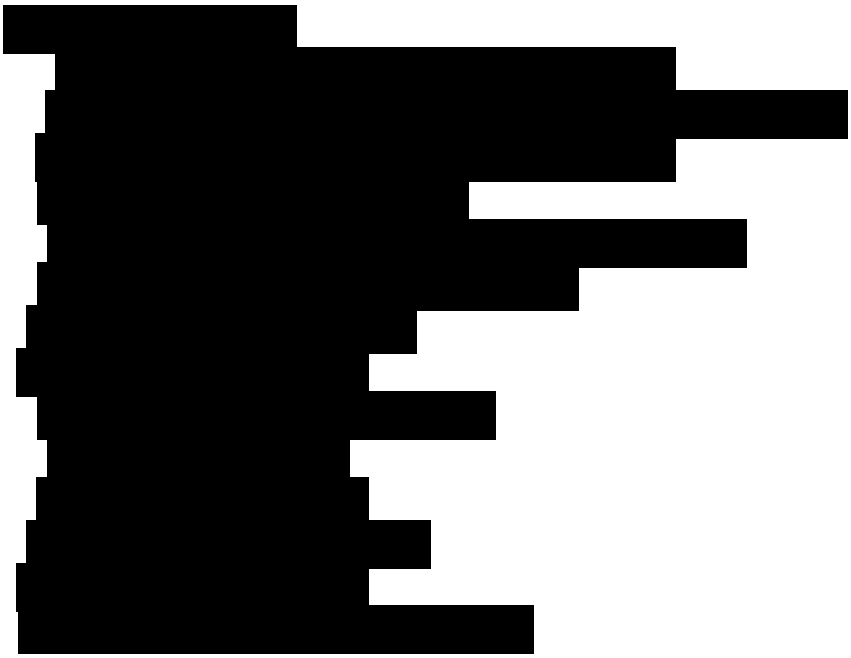
Table of Contents

1. Introduction and Qualifications

My name is Darren R. Hurst. I am a full time physician and fellowship-trained vascular and interventional radiologist. The discipline of vascular and interventional radiology involves the diagnosis, treatment, and management of medical diseases and health conditions through imaging and targeted, image-guided, minimally invasive surgical procedures. The procedures I perform involve the introduction of medical devices into the human body under image guidance such as ultrasound, CT, and fluoroscopy. Often, this involves the use of needles, guidewires, catheters, balloons, stents, drains, and other medical devices. My education, training, and experience are detailed in my CV which is in appendix A of this report. My practice is located in Edgewood, Kentucky and serves the Greater Cincinnati, Ohio area. I am familiar with the issues, subject matter, and topics involved in this litigation. I have personal experience with the use of both permanent and retrievable inferior vena cava ("IVC") filters for the prevention of pulmonary embolism. As part of my practice, I regularly implant and retrieve IVC filters. I am familiar with the relevant medical literature that addresses the issues concerning IVC filters, including but not limited to the indications and contraindications for use, placement, complications, and risks and benefits of the devices. I am also familiar with and have utilized multiple different types of filter devices including the Bard Simon Nitinol Filter®, Recovery Filter®, G2 Filter®, G2X Filter®, Eclipse®, and Denali Filter®. This experience, in combination with my education and training in the field of medicine and specifically the field of Vascular and Interventional Radiology, has formed the basis for my opinions rendered in this litigation.

2. Case Specific Materials Reviewed
    a. Medical Records:
        i. [redacted]
        ii. [redacted]

b. [redacted]



c. IFU
   i. Eclipse Filter
   ii. Bard G2 and G2x Filter
   iii. Bard Recovery Filter
   iv. Bard Simon Nitinol Filter

d. Bard Materials Reviewed:
   i. Internal Documents: See appendix.
   ii. Depositions: See appendix.

e. Medical Literature:
   i. See appendix.

f. Expert Reports
   i. Drs. Kinney, Roberts, and Kalva
   ii. Mark Eisenberg, M. D.

   I have reviewed these reports, I agree with them, and I adopt the opinions and bases for those opinions set forth therein.

3. Case [redacted]

[redacted]

4. Opinion:
    a. Summary:
        i. Doris Jones was [redacted]

        ii. [redacted]

[redacted].

b. Reasonable expectations of physicians for medical devices:
    i. In the everyday practice of medicine, I along with my colleagues and implanting and treating physicians have expectations of medical device companies like CR Bard and Bard Peripheral Vascular (referred to collectively in this report as "Bard") when they design, manufacture, market, and sell medical devices. Fulfilling these expectations in their design, testing, manufacturing, warning, and marketing of IVC Filters allows physicians to properly and completely obtain informed consent from their patients. Fulfillment of these expectations also allows physicians to select the appropriate IVC filter and make appropriate therapeutic decisions on behalf of their patients whether an IVC filter is indicated or considered as a therapeutic option, and whether to use or not use a particular type of IVC filter.

    ii. Moreover, a patient has reasonable expectations on what he or she should know in the same or similar circumstances as a reasonable patient who has been prescribed or has considered having an IVC filter implanted.

c. Informed Consent:
    i. The AMA Code of Medical Ethics - CHAPTER 2: OPINIONS ON CONSENT, COMMUNICATION & DECISION MAKING, *2.1.1 Informed Consent* states: Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to

participate in making decisions), physicians should: (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision. (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about: (i) the diagnosis (when known); (ii) the nature and purpose of recommended interventions; (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.

https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics- chapter-2.pdf.

ii. The AMA Code of Medical Ethics' Opinion 8.08 – Informed Consent states: The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information (see Opinion 8.122, "Withholding Information from Patients").

Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians need not communicate all information at one time, but should assess

the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate.

http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.

I have adopted the above AMA Codes in my daily practice and, in my opinion, they represent the standard of care relative to Informed Consent, Patient Communication, and Decision-Making.

d. Failure to notify:

i. Given the above responsibilities of a medical device manufacturer to the patient and the physician, and the physician to the patient, it is my opinion that Bard failed to notify the operating physicians and the implanted patients of the much higher complication rates associated with the Recovery®, G2x®, and Eclipse® filters in comparison to the original predicate device, the Simon Nitinol Filter®, and competitor filters. Instead, Bard continued to represent its filters as having superior safety, quality, and performance. (Example: G2 Brochure: "[G2 takes] strength and stability to a new level.")

ii. There were multiple early safety signals with the Recovery®, G2x®, and Eclipse® filters. These signals came from adverse event reports/sales data, from reports in the medical literature, from Bard's internal risk analyses, and from Bard's own in vitro testing indicating low migration resistance compared to other filters, and in some instances, failing to meet the minimum arbitrary threshold for migration resistance under a variety of foreseeable circumstances. For example, Bard's own internal risk analysis deemed the G2 filter to pose an "unacceptable risk" of caudal migration.

iii. Despite the above warning signs that the predicate device to [redacted], the G2 filter, had significant issues with safety, Bard continued to market the device for both permanent and retrievable indications in the prevention of PE from DVT. During this time, Bard acknowledged design

flaws that needed to be corrected, but instead chose to inappropriately utilize the data from the Grassi paper, and ignore their in-house studies, risk analysis, and the current medical literature, to justify the high complication rates and continued marketing practices. In essence, Bard chose to keep the product on the market until a new product was released rather than focusing on its duty to remove unsafe devices from the market.

iv. In addition, Bard marketing materials falsely represented newer generation devices as greatly improved strength and stability when many of the changes in the devices from generation to generation were minimal and unproven in their safety and efficacy.

v. Bard elected to not perform studies to further evaluate the safety, effectiveness, and durability of their filters. Instead, it embarked on a long-term plan to evolve its filter through multiple generations while making small incremental changes to each generation in response to the safety issues that were arising in real time in patients that were unknowingly participating in a decade-long open experiment with Bard retrievable filters.

vi. [redacted] No reasonably prudent physician would have. I would have also advised my partners and colleagues to do the same. It is my opinion that Bard did not adequately warn physicians, including Mrs. Jones's implanting physician, of important safety risks and issues associated with its filters of which it was aware. Moreover, the information disseminated by Bard was false and misleading about such risks, design, performance, effectiveness, and utility.

vii. [redacted] was the first Bard filter to add caudal anchors for the purpose of "improving caudal

migration resistance and tilt performance." As Bard was aware, the Eclipse filter was identical to the G2 and G2X filters with exception of electropolishing. Each of these filters suffered from a significant increased safety risk of caudal migration (a risk which Bard internally deemed "unacceptable") over competitor filters, and even earlier Bard filters (including the Simon Nitinol); Bard was aware of this information at the time Mrs. Jones was implanted with her filter. Bard was also aware at that time that caudal migration leads to tilt, perforation/penetration, complicated or high risk retrievals, and fracture. Bard initiated an internal project to correct caudal migration of the G2 filter beginning in February of 2006, a fact that was not passed on to physicians or patients, and made no changes to address those caudal migration problems until launch of the Meridian in August of 2011. Moreover, despite awareness of the need to correct the caudal migration problem with its filters, Bard launched the G2X and Eclipse, filters to which no changes were made to address the caudal migration safety risk, prior to launching the Meridian. Despite all of this, Bard continued selling the G2/G2X filter at the time it was implanted in Mrs. Jones and did not remove that filter from medical facilities. In my opinion, Bard should have never launched the G2/G2X filter without the safety design changes required by the unacceptable risk of caudal migration the company knew existed with the G2 by late 2005/early 2006 and/or should have recalled/removed that filter from the market. Mrs. Jones ultimately suffered from all of the G2/G2X filter complications the Meridian attempted to correct, including caudal migration, fracture, perforation, and tilt of the filter.

e. [redacted]:

i. [redacted]. Bard represented the Eclipse® IVC filter as a device that could be safely placed permanently or temporarily, provide effective protection from PE, and then could be easily removed

percutaneously without any time limitation. Given this backdrop, I render the following opinions:

1. [redacted]

2. [redacted] Given the dangerous location of the fragment is not amenable to be removed safely.

3. [redacted]

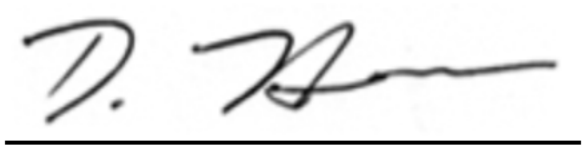
f. My opinions are based on the reasonable expectations that I and other similarly situated physicians have in regards to the responsibilities of a medical device manufacturer for the design**,** marketing, sales, and performance of their medical devices.

g. My opinions are based on my review of scientific and medical literature, the materials and medical records/films in this case, Bard internal documents, depositions, expert reports, and my clinical experience, education, and training. I did my own medical literature research and review, as well as reviewing literature provided to me by the plaintiff's counsel.

h. In rendering my opinions in this matter, I took into consideration Mrs. Jones's co-morbidities, medical history, and preexisting problems.

i. All of my opinions are to a reasonable degree of medical and scientific certainty.

j. I understand that discovery is ongoing in this case. There may be additional information in the form of medical literature, expert reports, depositions, and case material. I reserve the right to amend my opinions if further pertinent information is discovered/obtained.



Darren R. Hurst, M. D. 6/2/2017

APPENDIX

Bard Materials and Depositions Reviewed:

1. Janet Hudnall Email to David Rauch dated 2/26/04
2. Health Hazard Evaluation from David Ciavarella dated 12/17/04
3. G2 Perforations from Christopher Ganser dated 11/10/05
4. G2 Caudal Migrations from David Ciavarella dated 12/27/05
5. G2 Filter System - indicated for retrieval
6. G2 Filter System - Patient Questions & Answers
7. SWOT - Objective: Increase Revenue and Capture More Market Share
8. Monthly Global PV Report from John McDermott dated 2/10/06
9. Health Hazard Evaluation from David Ciavarella dated 2/15/06
10. G2 Caudal Migration Update dated 3/2/06
11. G2 Fracture Report November 2008
12. G2 and G2X Fracture Analysis dated 11/30/08
13. BARD IVC Filter Program May 2009 – Mike Randall
14. Letter from Stacy Taiber to Brent Adamson, M.D.
15. Filter Naming Memo from Bill Little dated 4/27/10
16. Eclipse 510(k) sections on changes to filter from predicate
17. Eclipse Product Performance Specification for Migration from Design History File

18. Meridian Product Performance Specification for Caudal Migration from Design History File

19. Meridian Value Proposition from Design History File

20. Meridian Commercialization Plan dated 10/1/10

21. G2 Platinum PowerPoint

22. Scott Karch Email to Dr. Thomas dated 3/6/12

23. Brian Barry Deposition - 1/31/14

24. Robert Michael Carr, Jr. Deposition - 4/17/13

25. Robert Michael Carr, Jr. Deposition - 10/29/14

26. Robert Michael Carr, Jr. Deposition - 11/5/13

27. Clement J. Grassi, M.D. Deposition - 7/30/14

28. Clement J. Grassi, M.D. Deposition - 8/27/14

29. Clement J. Grassi, M.D. Deposition - 9/24/14

30. Murray Asch, M.D. Deposition – 5/2/16

31. Kay Fuller Deposition – 1/11/16

32. David Ciavarella, M.D. Deposition – 11/12/13

33. Christopher Ganser Deposition – 10/11/16

34. Janet Hudnall Deposition – 11/1/13

35. John McDermott Deposition – 2/5/14

36. Gin Shultz Deposition – 1/30/14

37. Douglas Uelmen Deposition – 10/4/14

38. Carol Vierling Deposition – 5/11/16

39. Natalie Wong Deposition – 10/18/16

40. Steven Williamson Deposition – 9/7/16

41. Medical Monitoring 30(b)(6) Deposition (John Van Vleet) – 1/17/17

Literature Reviewed:

MEDICAL ARTICLES	
TITLE	AUTHOR(S)
Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study	Binkert
In Vitro Metal Fatigue Testing of Inferior Vena Cava Filters	Bjarnason
Comparison of the Recovery and G2 Filter as Retrievable Inferior Vena Cava Filters	Cantwell
Quality Improvement Guidelines for the Performance of Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Caplin
Complications Encountered with the Use of the Greenfield Filter	Carabasi
Prophylactic and Therapeutic Inferior Vena Cava Filters to Prevent Pulmonary Emboli in Trauma Patients	Carlin
Update on Vena Cava Filters	Carman
G2 Inferior Vena Cava Filter: Retrievability and Safety	Charles
Prophylactic Inferior Vena Cava Filters: Do They Make a Difference in Trauma Patients? (abstract only)	Cherry

Complications of vena cava filters: A comprehensive clinical review	Cipolla
TrapEase Inferior Vena Cava Filter Placed via the Basilic Arm Vein: A New Antecubital Access	Davison
Removal of Fractured Inferior Cava Filters: Feasibility and Outcomes	Dinglasan
Celect Inferior Vena Cava Wall Strut Perforation Begets Additional Strut Perforation	Dowell
Perforation of the IVC: Rule Rather Than Exception After Longer Indwelling Times for the Gunther Tulip and Celect Retrievable Filters	Durack
"Reporting the Impact of Inferior Vena Cava Perforation By Filters" JOURNAL OF VASCULAR SURGERY; Vol. 55, No. 1	Wood
PRESERVE Study to be a Comprehensive Evaluation of Inferior Vena Cava Filter use	Endovascular Today
Clinical Experience with the Antecubital Simon Nitinol IVC Filter	Engmann
Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use	FDA
Percutaneous Inferior Vena Caval Filters: Follow up of Seven Designs in 320 Patients	Ferris
Medical Literature and Vena Cava Filters	Girard
Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Grassi
Vena Caval Occlusion after Simon Nitinol Filter Placement: Identification with MR Imaging in Patients with Malignanacy	Grassi
Long-Term Follow-up of the Antheor Inferior Vena Cava Filter	Harries
Retrieval of the Recovery Filters after Arm Perforation, Fracture, and Migration to the Right Ventricle	Hull

Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration	Hull
Single Institution Prospective Evaluation of the Over-the-Wire Greenfield Vena Caval Filter	Johnson
Vena Cava Filter Fracture: Unplanned Obsolescence	Johnson
Decision Analysis of retrievable inferior vena cava filters in patients without pulmonary embolism	Morales
Recovery Vena Cava Filter: Experience in 96 Patients	Kalva
Practice Patterns and Outcomes of Retrievable Vena Cava Filters in Trauma Patients: an AAST Multicenter Study	Karmy-Jones
Guidelines for the Use of Optional (Retrievable and Convertible) Vena Cava Filters	Kaufman
Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference	Kaufman
Development of a Research Agenda for Inferior Vena Cava Filters: Proceedings from a Multidisciplinary Research Consensus Panel	Kaufman
Update on Inferior Vena Cava Filters	Kinney
High Risk Retrieval of Adherent IVC Filters: Techniques and Management of Thrombotic Complications	Kuo
High-Risk Retrieval of Adherent and Chronically Implanted IVC Filters: Techniques for Removal and Management of Thrombotic Complications	Kuo
Modified Loop Snare Technique for the Removal of Bard Recovery, G2, G2 Express, and Eclipse Inferior Vena Cava Filters	Lynch
Removal of the G2 filter: differences between implantation times	Lynch

greater and less than 180 days	
Complications of the Nitinol Vena Caval Filter	McCowan
Indications for Vena Cava Filters for Recurrent DVT	Miller
Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters	Millward
Improving Inferior Vena Cava Filter Retrieval Rates: Impact of a Dedicated Inferior Vena Cava Filter Clinic	Minocha
Realistic expectations and candidate selection for entry level vascular technologist in a busy laboratory	Mutyala
Letter to the Editor: A Complication of a G2 Bard Filter	Nazzal
Complications Related to Inferior Vena Cava Filters: A Single-Center Experience	Nazzal
Long-term Follow-up of the Bird's Nest IVC Filter	Nicholson
Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade	Nicholson
Refrain, Recover, Replace	Nicholson
Correction to Article About Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters	Nicholson
Removal of Retrievable Inferior Vena Cava Filters with Computed Tomography Findings Indicating Tenting or Penetration of the Inferior Vena Cava Wall	Oh
Recovery G2 Inferior Vena Cava Filter: Technical Success and Safety of Retrieval	Oliva

Recovery G2 vena cava filter retrievability study	Oliva
Intracardiac Migration of Inferior Vena Cava Filters	Owens
Long-term Results of the Simon Nitinol Inferior Vena Cava Filter	Poletti
Aortic Pseudoaneurysm after Penetration by a Simon Nitinol Inferior Vena Cava Filter	Putterman
Complications of Inferior Vena Cava Filters	Ray
Outcomes with Retrievable Inferior Vena Cava Filters: A Multicenter Study	Ray
Medical Devices and the FDA Approval Process	Redberg
Simon Nitinol Inferior Vena Cava Filter: Initial Clinical Experience	Simon
Vena Caval Filters	Smith
Is Market Growth of Vena Cava Filters Justified?	Smous
Embedded Inferior Vena Cava Filter Removal: Use of Endobronchial Forceps	Stavropoulos
Complications of Vascular Access Procedures in Patients with Vena Cava Filters	Streib
Fracture and Distant Migration of the Card Recovery® Filter: A retrospective Review of 363 Implantations for Potentially Life-Threatening Complications	Tam
Vena Tech Vena Cava Filter: Experience and Early Follow-Up	Taylor
Management if Severe Vena Cava Filter Tilting: Experience with Bard G-2 Filters	Turba
FDA Safety Communication: Removing Retrievable Inferior Vena Cava Filters	U.S. Food and Drug

	Administration
Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: Incidence, Clinical Consequences, and Outcomes of Removal Attempts	Vijay
Retrievability and Device-Related Complications of the G2® Filter: A Retrospective Study of 139 Filter Retrievals	Zhu

CV:

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Education:

- Fellowship in Vascular and Interventional Radiology
  University of Michigan Medical Center
  1999-2000

- Residency in Diagnostic Radiology
  University of Michigan Medical Center
  Dept. Award for Research Excellence 1999
  1995-1999

- Doctor of Medicine
  University of Cincinnati College of Medicine
  AOA Honor Society 1994-95
  1991-95

- B. A. in Zoology
  Miami University, Oxford, Ohio
  Cum Laude with University Honors
  1987-91

Employment Experience:

- Radiology Associates of Northern Kentucky
  Managing partner
  Regional multispecialty radiology and imaging group
  2001-Present

  Director Vascular & Interventional Associates
  Division of Radiology Associates of NKY
  Private practice VIR group
  2003-Present

Director VIA Vein Center
Comprehensive Vein Center
2013-Present

Chief of Vascular & Interventional Radiology
St. Elizabeth Health System
2003-Present

Director IR Spine Intervention
St. Elizabeth Spine Center
St. Elizabeth Health
2009-2016

Physician Trainer for Spine Intervention
Stryker International
2011-2015

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  859-344-2000

- St. Elizabeth Health
  Covington Campus
  401 East 20th Street
  Covington, Kentucky 41014
  859-292-4000

- St. Elizabeth Health
  Ft. Thomas Campus
  85 North Grand Avenue
  Ft. Thomas, Kentucky 41075
  859-572-3100

- St. Elizabeth Health
  Florence Campus
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  859-962-5200

Private Practice Office:

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  VIA Vein Center
  Center for Spine Health
  375 Thomas More Parkway
  Crestview Hills, KY 41017
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Certification:

- ABR Certified in General Diagnostic Radiology 1999

  ABR CAQ Board Certification
  Vascular and Interventional Radiology 2001

  ABR MOC/CAQ 10yr Recertification
  Vascular and Interventional Radiology 2011

- Kentucky License #35686
  Ohio License #4536
  Indiana License #010682666A

Professional Organizations:

RSNA: 1995
ARRS: 1995
ACR: 1998
SIS: 2010
SIR: 1999
ACP: 2015

Publications:

Hurst DR, Forauer AR, Bloom JR et al: Diagnosis and Endovascular Treatment of Iliocaval Compression Syndrome. J Vasc Surg 34(1):106-13, 2001.

Hurst DR, Kazerooni EA, Williams DM, Stafford-Johnson D, Platt JF, Prince MR: Diagnosis of Pulmonary Embolism: Comparison of MR Angiography and CT Angiography in Canines. *JVIR* 10:309-318, 1999.

Dong Q, **Hurst DR**, Wienmann HJ, Chenevert TL, Londy FJ, Prince MR: Magnetic Resonance Angiography With Gadomer-17: An Animal Study Original Investigation. *Investigative Radiology* 33:699-708, 1998.

Donnelly LF, **Hurst DR**, Strife JL, Shapiro RM: Plain Film Assessment of Pulmonary Flow in the Neonate with D-Transposition of the Great Vessels. *Pediatric Radiology* 25:195-7, 1995.

Research:

VOYAGER PAD Study: An international, multicenter, randomized, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularization procedures. Lead Investigator St. Elizabeth Health System 2014-present.

ATTRACT Study: a multicenter randomized trial to evaluate pharmacomechanical catheter-directed thrombolysis for the prevention of postthrombotic syndrome in patients with proximal deep vein thrombosis. Lead Investigator St. Elizabeth Health System 2013-present.

The CAPTURE registry: analysis of strokes resulting from carotid artery stenting in the post approval setting: timing, location, severity, and type. Co-investigator St. Elizabeth Health System 2005-2007.

The Fibroid Registry for outcomes data (FIBROID) for uterine embolization. Lead Investigator St. Elizabeth Health System 2001-2005.

References:

Brad Miller, M. D., President of Radiology Associates of Northern Kentucky, Saint Elizabeth Health, 859.331.5770

James Roebker, M. D., Chairman of Dept. of Radiology, Saint Elizabeth Health, 859.331.5770

David M. Williams, M. D., Professor of Radiology,Vascular and Interventional Radiology, University of Michigan Medical Center. 734.936.4483

James H. Ellis, M. D., Professor of Radiology, Associate Chairman of Department of Radiology, University of Michigan Medical Center. 734.936.4347

Prior testimony Darren R. Hurst, M. D.

1. Susan Gail Smith v. St. Mary's Medical Center et al. 8/11/2015
2. Barbara Bongiorno v. Phillip Adler M. D.; St. John Macomb Hospital

   1/21/2016
3. James Alley v. Hillcrest Medical Center et al. 3/15/16
4. Edith Fish v. Diallo et al. 11/7/2016
5. Austin v. CR Bard Inc. 8/19/16
6. Austin v. CR Bard Inc. 11/16/16

List of Fees

1. My current fee for the following medical legal activities is $500.00 per hour. This includes medical records review, review of depositions, literature searches, consultation time, preparation for deposition and trial testimony, oral or written reports, all travel time (billed as portal to portal), or any miscellaneous task as requested by client.
2. My current fee for all local deposition and trial activities is $750.00 per hour.
3. All out of area travel that requires an overnight stay is billed at $6000.00 per day. If I have to use a half day for travel or return from the location of trial or deposition, that will be billed at 3000.00 per half day. If I must cancel an entire office day to provide the requested services, an additional fee of $2000.00 per clinic/work day will be charged. Trial and out of area fees must be paid in advance of the date of travel.

REDACTED DOCUMENTS RELATED TO DOCKET 7302

Exhibit G – Filed Redacted

Exhibit G

Expert Report

Lisa Hyde v. CR Bard Inc.

Darren R. Hurst, M. D.
Director Vascular and Interventional Radiology
Department of Radiology
St. Elizabeth Health System
1 Medical Village Drive
Edgewood, KY 41017

TABLE OF CONTENTS

1. My name is Darren R. Hurst. I am a full time physician and fellowship trained vascular and interventional radiologist. The discipline of vascular and interventional radiology involves the diagnosis, treatment, and management of medical diseases and health conditions through imaging and targeted, image-guided, minimally invasive surgical procedures. The procedures I perform involve the introduction of medical devices into the human body under image guidance such as ultrasound, CT, and fluoroscopy. Often, this involves the use of needles, guidewires, catheters, balloons, stents, drains, and other medical devices. My education, training, and experience are detailed in my CV which is in appendix A of this report. My practice is located in Edgewood, Kentucky and serves the Greater Cincinnati, Ohio area. I am familiar with the issues, subject matter, and topics involved in this litigation. I have personal experience with the use of both permanent and retrievable inferior vena cava ("IVC") filters for the prevention of pulmonary embolism. As part of my practice, I regularly implant and retrieve IVC filters. I am familiar with the relevant medical literature that addresses the issues concerning IVC filters, including, but not limited to the indications and contraindications for use, placement, complications, and risks and benefits of the devices. I am also familiar with and have utilized multiple different types of filter devices including the Bard Simon Nitinol Filter®, Recovery Filter®, G2 Filter®, G2x Filter®, Eclipse®, and Denali Filter®. This experience, in combination with my education and training in the field of medicine, and specifically, the field of Vascular and Interventional Radiology, has formed the basis for my opinions rendered in this litigation.

2. **Case Specific Materials Reviewed**

   a. Medical Records:

      i. [redacted]

      ii. [redacted]

      iii. [redacted]

iv. [redacted]

[redacted]

vi. [redacted]

[redacted]

[redacted]

vii. [redacted]

viii. [redacted]

[redacted]

[redacted]

b. Imaging Reviewed:

i. [redacted]

ii. [redacted]

iii. [redacted]

iv. [redacted]

v. [redacted]

vi. [redacted]

vii. [redacted]

viii. [redacted]

c. IFU

i. Bard G2 and G2x Filter

ii. Bard Recovery Filter

iii. Bard Simon Nitinol Filter

d. Bard Materials Reviewed:

i. Internal Documents: See appendix.

ii. Depositions: See appendix.

e. Medical Literature:

i. See appendix.

f. Expert Reports

i. Drs. Kinney, Roberts, and Kalva

ii. Mark Eisenberg, M. D.

iii. I have reviewed these reports, I agree with them, and I adopt the opinions and bases for those opinions set forth therein.

3. Case Summary:

a. [redacted]

i. [redacted]

4. **Opinions:**

a. Summary:

i. [redacted]

ii. [redacted]

b. Reasonable Expectations of Physicians for Medical Devices:

i. In the everyday practice of medicine, I along with my colleagues/implanting and treating physicians have expectations of medical device companies like C.R. Bard, Inc. and Bard Peripheral Vascular (referred to collectively in this report as "Bard") when they design, manufacture, market, and sell medical devices. Fulfilling these expectations in their design, testing, manufacturing, warning, and marketing of IVC Filters allows physicians to properly and completely obtain informed consent from their patients. Fulfillment of these expectations also allows physicians to select the appropriate IVC filter and make appropriate therapeutic decisions on behalf of their patients whether an IVC filter is indicated or considered as a therapeutic option, and whether to use or not use a particular type of IVC filter.

ii. Moreover, a patient has reasonable expectations on what he/she should know in the same or similar circumstances as a reasonable patient who has been prescribed or has considered having an IVC filter implanted.

c. Informed Consent:

i. The AMA Code of Medical Ethics - CHAPTER 2: OPINIONS ON CONSENT, COMMUNICATION & DECISION MAKING, *2.1.1 Informed Consent* states: Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should: (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision. (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about: (i) the diagnosis (when known); (ii) the nature and purpose of recommended interventions; (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.

https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics- chapter-2.pdf.

ii. The AMA Code of Medical Ethics' Opinion 8.08 – Informed Consent states: The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information (see Opinion 8.122, "Withholding Information from Patients").

Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians

need not communicate all information at one time, but should assess the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate.

http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.

I have adopted the above AMA Codes in my daily practice and, in my opinion, they represent the standard of care relative to Informed Consent, Patient Communication, and Decision Making.

d. Failure to Notify:

i. Given the above responsibilities of the medical device manufacturer to the patient and the physician, and the physician to the patient, it is my opinion that Bard failed to notify the operating physicians and the implanted patients of the much higher complication rates associated with the Recovery®, G2x®, and Eclipse® filters in comparison to the original predicate device, the Simon Nitinol Filter®, and competitor filters. Instead, Bard continued to represent its filters as having superior safety, quality and performance. (Example: G2 Brochure: "…strength and stability to a new level.")

ii. There were multiple early safety signals with the Recovery®, G2x®, and Eclipse® filters. These signals came from adverse event reports/sales data, from reports in the medical literature, from Bard's internal risk analysis, and from Bard's own in vitro testing indicating low migration resistance compared to other filters, and in some instances, failing to meet the minimum arbitrary threshold for migration resistance under a variety of foreseeable circumstances. For example, Bard's own internal risk analysis deemed the G2 filter to pose an "unacceptable risk" of caudal migration.

iii. Despite the above warning signs that the predicate device to [redacted] During this time, Bard acknowledged design flaws that needed to be corrected, but instead chose to inappropriately utilize the data from the Grassi paper, and ignore their in-house studies, risk analysis, and the current medical literature, to justify the high complication rates and continued marketing practices. In essence, Bard chose to keep the product on the market until a new product was released rather than focusing on its duty to remove unsafe devices from the market.

iv. In addition, Bard marketing materials falsely represented newer generation devices as greatly improved strength and stability when many of the changes in the devices from generation to generation were minimal and unproven in their safety and efficacy.

v. Bard elected to not perform studies to further evaluate the safety, effectiveness, and durability of their filters. Instead, they embarked on a long-term plan to evolve their filter through multiple generations while making small incremental changes to each generation in response to the safety issues that were arising in real time in patients that were unknowingly participating in a decade long open experiment with Bard retrievable filters.

vi. [redacted] Each of these filters suffered from a significant increased safety risk of caudal migration (a risk which Bard internally deemed "unacceptable") over competitor filters, and even earlier Bard filters (including the Simon Nitinol); Bard was aware of this information at the time Ms. Hyde was implanted with her filter. Bard was also aware at that time that caudal migration leads to tilt, perforation/penetration, complicated or high risk retrievals and fracture. Bard initiated an internal project to correct caudal migration of the G2 filter beginning in February of 2006, a fact that was not passed on to physicians or patients, and making no changes to address those caudal migration problems until launch of the Meridian in August of 2011. Moreover, despite awareness of the need to correct the caudal migration problem with its filters, Bard launched the G2X and Eclipse, filters to which no changes were made to address the caudal migration safety risk, prior to launching the Meridian. Despite all of this, Bard continued selling the G2/G2X filter at the time it was implanted in Ms. Hyde, and did not remove that filter from medical facilities. In my opinion, Bard should have never launched the G2/G2X filter without the safety design changes required by the unacceptable risk of caudal migration the company knew existed with the G2 by late 2005/early 2006 and/or should have recalled/removed that filter from the market. [redacted].

vii. [redacted]s. No reasonably prudent physician would have. I would have also advised my partners and colleagues to do the same. It is my opinion that Bard did not adequately warn physicians, including Ms. Hyde's implanting physician, of important safety risks and issues associated with its filters of which it was aware. Moreover, the information disseminated by Bard was false and misleading about such risks, design, performance, effectiveness and utility.

e. [redacted]. Bard represented the G2x® IVC filter as a device that took "strength and stability to a new level" and could be safely placed temporarily or permanently, provide effective protection from PE, and then be easily removed percutaneously without any time limitation. Given this backdrop, I render the following opinions:

1. [redacted]

f. Basis of Opinions:

i. My opinions are based on the reasonable expectations I have and other similarly situated physicians have in regards to the responsibilities of a medical device manufacturer in regards to the design**,** marketing, sales, and performance of their medical devices.

ii. My opinions are based on my review of scientific and medical literature, the materials and medical records/films in this case, Bard internal documents, depositions, expert reports, and my clinical experience, education, and training. I did my own medical literature research and review, as well as reviewing literature provided to me by the plaintiff's counsel.

iii. In rendering my opinions in this matter, I took into consideration Ms. Hyde's co-morbidities, medical history, and preexisting problems.

iv. All of my opinions are to a reasonable degree of medical and scientific certainty.

v. I understand that discovery is ongoing in this case. There may be additional information in the form of medical literature, expert reports, depositions, and case material. I reserve the right to amend my opinions if further pertinent information is discovered/obtained.

Darren R. Hurst, M.D. 6/2/2017

APPENDIX

Bard Materials and Depositions Reviewed:

1. Janet Hudnall Email to David Rauch dated 2/26/04
2. Health Hazard Evaluation from David Ciavarella dated 12/17/04
3. G2 Perforations from Christopher Ganser dated 11/10/05
4. G2 Caudal Migrations from David Ciavarella dated 12/27/05
5. G2 Filter System - indicated for retrieval
6. G2 Filter System - Patient Questions & Answers
7. SWOT - Objective: Increase Revenue and Capture More Market Share
8. Monthly Global PV Report from John McDermott dated 2/10/06
9. Health Hazard Evaluation from David Ciavarella dated 2/15/06
10. G2 Caudal Migration Update dated 3/2/06
11. G2 Fracture Report November 2008
12. G2 and G2X Fracture Analysis dated 11/30/08
13. BARD IVC Filter Program May 2009 – Mike Randall
14. Letter from Stacy Taiber to Brent Adamson, M.D.
15. Filter Naming Memo from Bill Little dated 4/27/10
16. Eclipse 510(k) sections on changes to filter from predicate
17. Eclipse Product Performance Specification for Migration from Design History File
18. Meridian Product Performance Specification for Caudal Migration from Design History File
19. Meridian Value Proposition from Design History File

20. Meridian Commercialization Plan dated 10/1/10
21. G2 Platinum PowerPoint
22. Scott Karch Email to Dr. Thomas dated 3/6/12
23. Brian Barry Deposition - 1/31/14
24. Robert Michael Carr, Jr. Deposition - 4/17/13
25. Robert Michael Carr, Jr. Deposition - 10/29/14
26. Robert Michael Carr, Jr. Deposition - 11/5/13
27. Clement J. Grassi, M.D. Deposition - 7/30/14
28. Clement J. Grassi, M.D. Deposition - 8/27/14
29. Clement J. Grassi, M.D. Deposition - 9/24/14
30. Murray Asch, M.D. Deposition – 5/2/16
31. Kay Fuller Deposition – 1/11/16
32. David Ciavarella, M.D. Deposition – 11/12/13
33. Christopher Ganser Deposition – 10/11/16
34. Janet Hudnall Deposition – 11/1/13
35. John McDermott Deposition – 2/5/14
36. Gin Shultz Deposition – 1/30/14
37. Douglas Uelmen Deposition – 10/4/14
38. Carol Vierling Deposition – 5/11/16
39. Natalie Wong Deposition – 10/18/16
40. Steven Williamson Deposition – 9/7/16
41. Medical Monitoring 30(b)(6) Deposition (John Van Vleet) – 1/17/17

Literature Reviewed:

MEDICAL ARTICLES	
TITLE	AUTHOR(S)
Technical Success and Safety of Retrieval of the G2 Filter in a Prospective, Multicenter Study	Binkert
In Vitro Metal Fatigue Testing of Inferior Vena Cava Filters	Bjarnason
Comparison of the Recovery and G2 Filter as Retrievable Inferior Vena Cava Filters	Cantwell
Quality Improvement Guidelines for the Performance of Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Caplin
Complications Encountered with the Use of the Greenfield Filter	Carabasi
Prophylactic and Therapeutic Inferior Vena Cava Filters to Prevent Pulmonary Emboli in Trauma Patients	Carlin
Update on Vena Cava Filters	Carman
G2 Inferior Vena Cava Filter: Retrievability and Safety	Charles
Prophylactic Inferior Vena Cava Filters: Do They Make a Difference in Trauma Patients? (abstract only)	Cherry
Complications of vena cava filters: A comprehensive clinical review	Cipolla
TrapEase Inferior Vena Cava Filter Placed via the Basilic Arm Vein: A New Antecubital Access	Davison
Removal of Fractured Inferior Cava Filters: Feasibility and Outcomes	Dinglasan
Celect Inferior Vena Cava Wall Strut Perforation Begets Additional Strut Perforation	Dowell
Perforation of the IVC: Rule Rather Than Exception After Longer Indwelling Times for the Gunther Tulip and Celect Retrievable Filters	Durack
"Reporting the Impact of Inferior Vena Cava Perforation By Filters"	Wood

JOURNAL OF VASCULAR SURGERY; Vol. 55, No. 1	
PRESERVE Study to be a Comprehensive Evaluation of Inferior Vena Cava Filter use	Endovascular Today
Clinical Experience with the Antecubital Simon Nitinol IVC Filter	Engmann
Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use	FDA
Percutaneous Inferior Vena Caval Filters: Follow up of Seven Designs in 320 Patients	Ferris
Medical Literature and Vena Cava Filters	Girard
Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism	Grassi
Vena Caval Occlusion after Simon Nitinol Filter Placement: Identification with MR Imaging in Patients with Malignancy	Grassi
Long-Term Follow-up of the Antheor Inferior Vena Cava Filter	Harries
Retrieval of the Recovery Filters after Arm Perforation, Fracture, and Migration to the Right Ventricle	Hull
Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration	Hull
Single Institution Prospective Evaluation of the Over-the-Wire Greenfield Vena Caval Filter	Johnson
Vena Cava Filter Fracture: Unplanned Obsolescence	Johnson
Decision Analysis of retrievable inferior vena cava filters in patients without pulmonary embolism	Morales
Recovery Vena Cava Filter: Experience in 96 Patients	Kalva
Practice Patterns and Outcomes of Retrievable Vena Cava Filters in Trauma Patients: an AAST Multicenter Study	Karmy-Jones
Guidelines for the Use of Optional (Retrievable and Convertible) Vena Cava Filters	Kaufman
Guidelines for the Use of Retrievable and Convertible Vena Cava Filters:	Kaufman

Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference	
Development of a Research Agenda for Inferior Vena Cava Filters: Proceedings from a Multidisciplinary Research Consensus Panel	Kaufman
Update on Inferior Vena Cava Filters	Kinney
High Risk Retrieval of Adherent IVC Filters: Techniques and Management of Thrombotic Complications	Kuo
High-Risk Retrieval of Adherent and Chronically Implanted IVC Filters: Techniques for Removal and Management of Thrombotic Complications	Kuo
Modified Loop Snare Technique for the Removal of Bard Recovery, G2, G2 Express, and Eclipse Inferior Vena Cava Filters	Lynch
Removal of the G2 filter: differences between implantation times greater and less than 180 days	Lynch
Complications of the Nitinol Vena Caval Filter	McCowan
Indications for Vena Cava Filters for Recurrent DVT	Miller
Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters	Millward
Improving Inferior Vena Cava Filter Retrieval Rates: Impact of a Dedicated Inferior Vena Cava Filter Clinic	Minocha
Realistic expectations and candidate selection for entry level vascular technologist in a busy laboratory	Mutyala
Letter to the Editor: A Complication of a G2 Bard Filter	Nazzal
Complications Related to Inferior Vena Cava Filters: A Single-Center Experience	Nazzal
Long-term Follow-up of the Bird's Nest IVC Filter	Nicholson
Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade	Nicholson
Refrain, Recover, Replace	Nicholson

Correction to Article About Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters	Nicholson
Removal of Retrievable Inferior Vena Cava Filters with Computed Tomography Findings Indicating Tenting or Penetration of the Inferior Vena Cava Wall	Oh
Recovery G2 Inferior Vena Cava Filter: Technical Success and Safety of Retrieval	Oliva
Recovery G2 vena cava filter retrievability study	Oliva
Intracardiac Migration of Inferior Vena Cava Filters	Owens
Long-term Results of the Simon Nitinol Inferior Vena Cava Filter	Poletti
Aortic Pseudoaneurysm after Penetration by a Simon Nitinol Inferior Vena Cava Filter	Putterman
Complications of Inferior Vena Cava Filters	Ray
Outcomes with Retrievable Inferior Vena Cava Filters: A Multicenter Study	Ray
Medical Devices and the FDA Approval Process	Redberg
Simon Nitinol Inferior Vena Cava Filter: Initial Clinical Experience	Simon
Vena Caval Filters	Smith
Is Market Growth of Vena Cava Filters Justified?	Smous
Embedded Inferior Vena Cava Filter Removal: Use of Endobronchial Forceps	Stavropoulos
Complications of Vascular Access Procedures in Patients with Vena Cava Filters	Streib
Fracture and Distant Migration of the Card Recovery® Filter: A retrospective Review of 363 Implantations for Potentially Life-Threatening Complications	Tam
Vena Tech Vena Cava Filter: Experience and Early Follow-Up	Taylor
Management if Severe Vena Cava Filter Tilting: Experience with Bard G-2 Filters	Turba
FDA Safety Communication: Removing Retrievable Inferior Vena Cava	U.S. Food and

Filters	Drug Administration
Fractured Bard Recovery, G2, and G2 Express Inferior Vena Cava Filters: Incidence, Clinical Consequences, and Outcomes of Removal Attempts	Vijay
Retrievability and Device-Related Complications of the G2® Filter: A Retrospective Study of 139 Filter Retrievals	Zhu

CV:

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Education:

- Fellowship in Vascular and Interventional Radiology
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- Residency in Diagnostic Radiology
  University of Michigan Medical Center
  Dept. Award for Research Excellence 1999
  1995-1999

- Doctor of Medicine
  University of Cincinnati College of Medicine
  AOA Honor Society 1994-95
  1991-95

- B. A. in Zoology
  Miami University, Oxford, Ohio
  Cum Laude with University Honors
  1987-91

Employment Experience:

- Radiology Associates of Northern Kentucky
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  2003-Present

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  2013-Present

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2003-Present

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2009-2016

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2011-2015

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David M. Williams, M. D., Professor of Radiology, Vascular and Interventional Radiology, University of Michigan Medical Center. 734.936.4483

James H. Ellis, M. D., Professor of Radiology, Associate Chairman of Department of Radiology, University of Michigan Medical Center. 734.936.4347

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6. Austin v. CR Bard Inc. 11/16/16

List of Fees

1. My current fee for the following medical legal activities is $500.00 per hour. This includes medical records review, review of depositions, literature searches, consultation time, preparation for deposition and trial testimony, oral or written reports, all travel time (billed as portal to portal), or any miscellaneous task as requested by client.
2. My current fee for all local deposition and trial activities is $750.00 per hour.
3. All out of area travel that requires an overnight stay is billed at $6000.00 per day. If I have to use a half day for travel or return from the location of trial or deposition, that will be billed at 3000.00 per half day. If I must cancel an entire office day to provide the requested services, an additional fee of $2000.00 per clinic/work day will be charged. Trial and out of area fees must be paid in advance of the date of travel.